EXHIBIT AA

Prof. Dr. Dres. h.c. Joseph Straus

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October 4, 2006
Str/ma

Dear Li,

Though under such tremendous time pressure, I was able to in the meantime accomplish the requested statement on behalf of Bavarian Nordic. I am sending it to you, here via facsimile and, tomorrow, by regular mail.

Best wishes,

Joseph Straus

Enclosure (15 pages)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S,

Plaintiff,

v.

ACAMBIS INC. and
ACAMBIS PLC,

Defendants.

Civil Action No. 05-614 (SLR)

EXPERT REPORT AND/OR LEGAL OPINION OF

PROF. DR. DRES. H.C. JOSEPH STRAUS

I. INTRODUCTION

1. My name is Joseph Straus and I have been retained as a legal expert on German Law by Bavarian Nordic A/S ("BN") in connection with the above-referenced case in the United States District Court for the District of Delaware to study and provide opinion on certain issues relating to ownership to and/or intellectual property rights in certain Modified Vaccinia Virus Ankara ("MVA") strains and vaccines.

2. I understand that BN alleges conversion with respect to certain live biological material based on the use of BN's proprietary MVA-572 strain as the precursor for developing, producing and selling the MVA3000 vaccine product at issue in this investigation.

II. QUALIFICATIONS

3. I am the Director of the Max Planck Institute for Intellectual Property, Competition and Tax Law in Munich, and Professor of Law at the Universities of Munich and Ljubljana, in Germany and Slovenia respectively. I earned a Law Diploma in 1962 from the University of Ljubljana, Slovenia, and a Dr. jur. from Ludwig-Maximilians-Universität, in Munich in 1968. I worked in private practice from 1968 to 1977. Since then, I have worked at the Max Planck Institute. I have taught European and German Patent Law at Ludwig-Maximilians-Universität, Munich since 1990. Beginning in 1989 I have been a Visiting Professor of Law at Cornell Law School, Ithaca, N.Y., teaching accelerated courses on International Protection of Intellectual Property Rights. I was also a Visiting Professor at the George Washington University Law School in 2001 and 2002, and am the Marshall B. Coyne Visiting Professor of International and Comparative Law at the same institution, regularly teaching courses on biotech and chemical patents. Moreover, I was a Distinguished Visiting Professor at the Faculty of Law, University of Toronto in Spring 2005.

4. I am a former President of the International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP); Vice President of the German Association for the Protection of Industrial Property and Copyright Law (GRUR); Chair of the Program Committee of the International Association for the Protection of Intellectual Property (AIPPI); Chair of the Intellectual Property Rights Committee of the Human Genome Organisation (HUGO); 1999 Katz-Kiley Fellow of the University of Houston Law Center; and an Arbitrator with the International Court of Arbitration of the International Chamber of Commerce, Paris. I have served as a consultant to OECD, WIPO, UNCTAD, UNIDO, EC-Commission, World Bank, Scientific Services of the German Bundestag, the European Patent

Organisation, the Swiss Federal Government and the Swiss Federal Institute of Intellectual Property. I have authored or co-authored numerous publications in the field of intellectual property law. I am a recipient of many awards and honorary degrees.

5. I am a member in the following advisory bodies and scientific organisations: Standing Advisory Committee before the European Patent Organisation (SACEPO); Advisory Board of the Worldwide Academy of the World Intellectual Property Organisation (WIPO); Standing Committee "Intellectual Property Rights" All European Academies (ALLEA); Executive Council of the Center for Advanced Study and Research on Intellectual Property (CASRIP) of the University of Washington, School of Law, Seattle; Advisory Council of the McCarthy Institute for Intellectual Property and Technology Law, University of San Francisco, School of Law, San Francisco and International Board of Assessors of the Intellectual Property Research Center, University of Melbourne; Corresponding Member of the Slovenian Academy of Science and Art; Member of the Academia Europaea; and Member and Dean of the Class for Social, Legal and Economic Sciences of the European Academy of Sciences and Arts. I actively research such areas as European and International Patent Law, International Protection of Intellectual Property Rights, Technology Transfer, and employee's inventions.

6. I have provided legal opinions in a great number of patent cases litigated for instance in Dutch, German, Italian, Japanese, Slovenian, Swiss and U.S. courts for companies such as Bayer, Dade-Behring, Boehringer Ingelheim, Glaxo-Wellcome, Merck, Novartis, Pfizer, Roche, SmithKline Beecham, Texas Instruments, 3M and others. Upon request of the German and Austrian Government I testified before competent committees of the respective Parliaments, and at the request of the European Commission, before the Committee on Legal Affairs and Citizen Rights of the European Parliament, on various issues of patent law, especially on biotech

patents.

7. I am being compensated in this matter at my usual hourly rate, in addition to reimbursement for out-of-pocket expenses. My right to compensation is in no way contingent upon the outcome of the case or any issue in it. I have never testified as an expert and have not been deposed for trial. Further, I have not been retained as or testified as an expert on this subject matter in any other litigation.

8. In forming the opinions expressed below, I have reviewed and relied at least on certain documents listed in Exhibit A and my legal expertise in German law (cf. e.g. *Straus/Moufang*, Deposit and Release of Biological Material for the Purposes of Patent Procedure, Baden Baden 1990).

III. EXPECTED TESTIMONY AND OPINIONS

9. BN's proprietary rights relate to the MVA vaccine stock and MVA viral stock developed by and/or in the possession of Prof. Mayr, including without limitation property rights, intellectual property rights, and damage and royalty claims for uses of MVA and know how pertaining thereto, and comprises claims for compensation against third parties accruing pre and post transfer of these rights to Bavarian Nordic in 2002.

10. I am prepared to testify that under German law no transfer of rights occurred between Prof. Mayr and Dr. Moss and/or NIH with respect to MVA-572 and/or its progeny, either as a direct transfer or based on good faith receipt.

11. I am prepared to testify that under German law no transfer of ownership rights, or commercial rights, took place between Prof. Mayr or BN to Dr. Moss and/or NIH with respect to MVA-572 and/or its progeny, as a direct transfer or based on bona fide purchase.

12. I am also prepared to testify that under German law no transfer of ownership rights, or commercial rights, took place between Prof. Mayr or BN and/or Dr. Moss and/or NIH to Acambis with respect to MVA-572 and/or its progeny, as a direct transfer or based on bona fide purchase.

IV. MY OPINION REGARDING OWNERSHIP OF BIOLOGICAL MATERIAL

13. This case concerns a man-made virus known as Modified Vaccinia Ankara ("MVA"), which is a member of the genera Orthopoxvirus in the family of Poxviridae. The MVA virus was created by the German Prof. Anton Mayr in Germany through a process of 516 serial passages of the Chorioallantoic Vaccina Ankara (CVA) strain on chicken embryo fibroblasts (CEF) cells (*see Mayr, A., Hochstein-Mintzel, V.* and *Stickl, H.* [1975] Infection 3, 6-14). As a consequence of these long term passages, the resulting MVA virus deleted about 31 kilobases of its genomic sequence and, therefore was described as highly host cell restricted to avian cells (*Meyer, H. et al.*, J.Gen. Virol. 72, 1031-1038[1991]). It was shown in a variety of animal models that the resulting MVA was significantly avirulent (Mayr, A. & Danner, K. [1978] Dev. Biol. Stand. 41: 225-34).

14. Prof. Mayr developed the MVA virus from CVA over a time period of several years. First while being the Director of the Department of Microbiology at the Federal Research Institution for Virus Diseases in Animals, Tübingen, Germany between 1955-1959, and then as the President of the same institute in 1959-1963. Prof. Mayr continued this work towards creating the MVA virus as the Director of the Institute for Medical Microbiology, Infectious and Epidemic Diseases, Veterinary Faculty, University of Munich, Germany, 1963-1991. In the

early 1970-ies, Prof. Mayr reached the 516th passage and renamed the virus into MVA.

15. Before addressing the ownership of Professor Mayr in the virus MVA, it should be clarified that under the applicable German law it is irrelevant for the issue of property rights whether the physical object is animate or inanimate. Consequently, there can be no doubt that micro-organism cultures are "tangible goods" from the point of view of property law. Ownership in such tangible goods can be acquired by assignment by means of a legal transaction, acquisition of an ownerless tangible good, treasure trove, manufacture of new tangible goods, combining, and mixing (commingling). The proprietor of a tangible good automatically acquires title to its products (and other component parts) as a matter or principle. Thus the property right covers also those micro-organisms that were removed from the original culture and have been reproduced further. This right is not restricted just to leaving products, however, but also applies, for example, to extracted metabolic products of micro-organisms and monoclonal antibodies produced from hybridoma cell lines. For the definition of the term "product", it is irrelevant whether the production process is caused by nature alone or is based on the result of human labor. Title could at most be lost if the owner of the biological material were to produce a new tangible good by processing or converting it. Under German tangible property law, however, this would presuppose that a result were achieved which displayed new properties as compared to the starting material and which constituted a new and independent asset. Whether a third party who uses biological material that is not his property to produce valuable substances "manufactures new tangible goods" and thus acquires title to the substances depends on the concrete facts of the individual case. The position resulting from the title to the biological material does not only provide the proprietor with remedies against unauthorized possessors. Rather, he can also utilize it by reserving title within the framework of licensing agreements (cf. *Straus/Moufang*, op. cit.,

pp. 96-100 with numerous further references).

16. Under the German laws applicable to the facts of this case, a consequence of Article 5 III of the German Constitution (Grundgesetz – GG), in which the freedom of research is guaranteed and which, in the context of the issue at hand, also covers the right of exploitation and the respective exploitation activities, guaranteed under Articles 2, 12, 14 at Seq. GG (*Frieling*, Forschungstransfer: Wem gehören Forschungsergebnisse [Research Transfer: To Whom Belong Research Results], 1987 GRUR 407 at Seq., at 408), was that tangible as well as intangible results of the research work of a university professor belonged to the professor (*Frieling* 1987 GRUR 408 at seq.). It was up to the professor to take the decision whether and in which form to exploit own research results (*Ullrich*, Privatrechtsfragen der Forschungsförderung in der Bundesrepublik Deutschland [Civil Law Issues of Research Promotion in the Federal Republic of Germany], 1984, p. 290). In respect to inventions made by German university professors before February 7, 2002, the German Law on Employees Inventions in its Section 42 explicitly provided that "inventions made by professors, lecturers and scientific assistants, in their capacity as such, at universities and higher schools of science shall be free inventions." Since the facts at hand in this case all occurred before February 2, 2002, no need exists to examine the impact of the new law, neither in the context of tangible nor intellectual property.

17. It is undisputed under the German law that tangible scientific research results, including naturally occurring substances such as bacteria or viruses, at least if they are limited in space, either by their own physical delimitations, or by being placed in a container or by some other artificial means, can be subject matter of tangible property rights (*Straus/Moufang*, op. cit., p. 96 and footnote 265 with further references). It is further undisputed that where the scientific and economic value of a research result is inseparably attached to the originally discovered or

arranged tangible object, either because its reproduction is not possible, too expensive or too complicate, and especially if it can be achieved only by the reproduction of the object, i.e. of the micro-organisms itself, the exploitation interest of the researcher is expressed in his discretionary control over the object (*Frieling*, 1987 GRUR 410).

18. As indicated above (No. 15) tangible property in biological material can be acquired by means of a legal transaction, acquisition of an ownerless tangible good, treasure trove, manufacture of a new tangible good, combining, and mixing (commingling). Isolating or genetically altering a micro-organism is viewed as being tantamount to manufacturing a new tangible good, to which the researcher acquires title under Section 950 BGB (German Civil Code), provided the entire economic value of the exploitation potential of the further processed tangible research result is not much less than that of the starting material (*Frieling*, 1987 GRUR 410, 411, who uses as an example in vitro bred viral lines [Virenstämme] as compared with single viruses. Thanks to adding and mixing single viruses with nutrient substrates, viruses acquire the ability of continuous reproduction).

19. Since a university professor, due to his status guaranteed independence (Section 43 of the Law on Higher Eduction [Hochschulrahmengesetz - HRG]) cannot be directed to a specific result of his work by the employer, his right to individually take initiative for research activities always prevails, with the consequence that he has the right to dispose over tangible results of his research work. This is true even if the raw materials used for manufacture were put at his disposal by the University. In this context the property right in the raw material is viewed to be vanished (*Frieling*, 1987 GRUR 412: "Daran ändert sich ohne weiteres nichts, wenn die Materialien für die Herstellung von der Hochschule bereitgestellt wurden. Das Eigentum an den Rohstoffen geht regelmäßig gemäß § 950 II BGB unter").

20. As indicated above, Professor Mayr developed MVA virus from CVA over a lengthy period of time. It appears beyond doubt and does not seem to be disputed that he, when he in 1963 became director of the Institute for Medical Microbiology, Infectious and Epidemic Diseases at the Veterinary Faculty of the Ludwig-Maximilians-University in Munich, brought into his new lab CVA samples, which had undergone already considerable numbers of passages. Quite apart from the fact that his former employers, namely the Bavarian Vaccine Institute in Munich and the Federal Research Institute for Virus Diseases in Animals, Tübingen, never raised any tangible property claims in CVA samples of Professor Mayr's lab, their property in CVA, had it ever existed, would have vanished in view of the results of the further research work of Professor Mayr in that material. As I understand, the successful and decisive creative work of Professor Mayr was performed during his time as Professor and Director of the Munich University Institute for Medical Microbiology, Infectious and Epidemic Diseases in the early 1970-ies, when he reached the 516th passage and renamed the virus into MVA. MVA, unlike its predecessors, due to deletion of some 31 kilobases of its genomic sequence, became highly host cell restricted to avian cells and was significantly avirulent (*supra* no. 11). From the general interest demonstrated in MVA from so many prominent sides worldwide, it clearly follows, that MVA displayed new, important and in view of its purposive use, decisive properties as compared to the CVA as starting material. It also follows from that fact that MVA constituted from the very beginning a new and independent asset, exclusively owned by Professor Mayr.

21. MVA-571 (Prof. Mayr's 571 serial passage strain of MVA) was registered in 1976 in Germany. This MVA virus was used at a very low dose as a pre-vaccine before administering the conventional smallpox vaccine and shown to be safe in that dose in more than 120,000 individuals, including at-risk subjects for smallpox vaccination. The clinical trials were

conducted by a medical doctor named Stickl through the Bavarian Vaccine Institute (Bayer Landesimpfanstalt) Munich in collaboration with Prof. Mayr. As a clinician, Dr. Stickl obviously never passaged or plaque purified the virus. Prof. Mayr was the virologist and he was always the one who worked with the virus itself. Based on this collaboration, however, the MVA strain was tested in clinical trials as a vaccine to immunize against the human smallpox disease (*Mayr et al.*, Zbl. Bakt.Hyg. I, Abt.Org. B 167, 375-390 [1987], *Stickl et al.*, Dtsch. med. Wschr. 99, 2386-2392 [1974]). The Defendant has suggested that ownership somehow could have transferred to Dr. Stickl based on the clinical testing conducted at the Bayer Landesimpfanstalt and the subsequent use of MVA as a pre-vaccine in Germany. I disagree.

22. Specifically, ownership of the MVA viruses created by Prof. Mayr did not at any point transfer to Dr. Stickl based on the mere provisions of MVA viruses for clinical trials, or vaccinations of the general population as suggested by Acambis. The record reveals no separate transfer of ownership from Prof. Mayr to Dr. Stickl. At any rate, this aspect is irrelevant as I understand this case to concerns a specific MVA virus, namely the MVA-572 virus delivered from Prof. Mayr to Dr. Moss and not any MVA potentially existing at the Bavarian Vaccine Institute. Accordingly, I will focus on the specific MVA-572 virus which is relevant to this case that Prof. Mayr per request provided to Dr. Moss at the NIH.

V. MY OPINION REGARDING TRANSFER OF RIGHTS TO MVA-572 BETWEEN PROF. MAYR AND BAVARIAN NORDIC

23. Prof. Anton Mayr and Bavarian Nordic originally entered into a license agreement in 1996 that provided Bavarian Nordic "exclusive and sole access to" Mayr's MVA stocks, with the provision that "in the scientific community, there is a growing interest in

performing basic non-commercial research including the MVA vector. BN agrees not to unreasonably use its exclusivity to the MVA system to hinder basic research by third party non-commercial academia." Mayr and Bavarian Nordic entered into additional agreements regarding Mayr's MVA vaccine stock in 1999, 2001, 2003 and 2004.

24. In 2002, Mayr entered into an Assignment Agreement with Bavarian Nordic. In the recitals, the Assignment Agreement confirms that Mayr "previously granted BN . . . exclusive access to MVA vaccine stock and MVA viral stock" and further confirms "transfer of ownership of all MVA vaccine stock and MVA viral stock in the possession of Dr. Mayr ('MVA strains') to BN." After the recitals, the Assignment Agreement transfers from Mayr to Bavarian Nordic the "entire right, title and interest in and to said MVA Strains and Patents . . . and all and every right to make commercial use of the MVA Strains." The MVA viruses assigned include MVA-572.

25. It is my opinion that Prof. Mayr transferred title to BN with respect to all MVA strains including the MVA-572 based on the 2002 agreement between Anton Mayr and BN, unless rights have been transferred to a third party prior to this date based on a concrete agreement to that effect. Accordingly, Prof. Mayr had no rights to transfer with respect to any MVA strains, including MVA-572 to third parties after he transferred his rights to BN.

26. It is my opinion that Prof. Mayr's transfer of his rights regarding ownership and royalty claims with respect to any commercialisation of MVA strains covers all MVA strains being provided by him to third parties for research purposes. Accordingly, BN legally stands in the shoes of Prof. Mayr and any right Prof. Mayr has in any particular MVA strain is the rights of BN.

VI. MY OPINION REGARDING TRANSFER OF OWNERSHIP

27. According to German law, a receiver of an MVA strain owned by BN would only be free to use that MVA-strains commercially based on either a transfer of ownership or an explicit agreement regarding commercial use of the strain at issue. The relevant strain is the MVA-572, which was provided to Dr. Moss at the National Institute of Health ("NIH") in August 2001.

28. According to German law, a transfer of ownership does not take place by a mere provision of an MVA strain by an owner to a third party. In fact, ownership to the MVA-572 cannot be transferred solely based on right of use or a sales contract.

29. German law requires a separate transfer of ownership.

30. According to the so-called *Abstraktionsprinzip* both these transactions (*i.e.* sales contract and transfer of ownership) are legally independent transactions.

31. Absent an explicit and separate transfer of ownership, Dr. Moss and/or NIH would not be permitted to use the MVA-572 strain or its progeny for commercial purposes. Particularly, the record fails to demonstrate an explicit and separate transfer of ownership to Dr. Moss or the NIH. To the contrary, the record shows that Prof. Mayr provided the MVA-572 strain to Dr. Moss for research purposes only.

32. A provision of an MVA-572 strain for research purposes certainly does not automatically qualify as a transfer of rights for commercial purposes unless there is a specific agreement between the parties to that effect, either explicitly or based on research or industry practice. With respect to research and industry practices, live biological material, such as a MVA strain, provided to a research institution for research purposes cannot be used for

commercial purposes without an explicit agreement to that effect.

33. Prof. Mayr has a well recognized duty in the scientific community based on his numerous publications in renowned scientific journals to provide the MVA virus to interested parties for research purposes. As one example of many, see *Meyer, H., Sutter, G., and Mayr, A.* "Mapping of deletions in the genome of the highly attenuated vaccinia virus MVA and their influence on virulence" J.Gen.Virol., 72 (Pt 5), 1031-1038. 1991. As specifically revealed from the Instructions for Authors (at p. 8, lines 24-28), "By publishing in JGV, authors agree that any viruses, plasmids and living materials, such as cell lines or bacterial strains that are newly described within the article are available without unnecessary delay and at a reasonable cost to members of the scientific community for non-commercial purposes." (See also generally, *e.g.*; ". . . and material/information must be made available, to permit the work to be repeated by others." And further; "Supply of materials . . . and must be for legitimate, bona fide research needs." J. Gen. Virology Instructions to Authors at p. 2, l. col. ,lines 11-18.) Moreover, Dr. Moss acknowledged the restrictions on the transfer of MVA-572 from Prof. Mayr when he required Therion Biologics Corporation, a for-profit company, to first acquire Prof. Mayr's permission before providing the strain (see letter of Therion Biologics of February 26, 2002).

34. Prof. Mayr deposited the MVA-572 virus at the European Collection of Animal Cell Cultures ("ECACC") under number V940012707, thus, making this virus available to the research community for research purposes only.

35. Accordingly, Dr. Moss and/or NIH had no right to provide the MVA-572 or its progeny to Acambis as per the Material Transfer Agreement dated 9 September 2002. This MTA also explicitly provides no warrant regarding freedom to operate and includes an indemnification clause to the benefit of the NIH.

36. If called, I will testify that, in my opinion, according to Section 929 of the German Civil Code (BGB), a transfer of ownership requires an agreement of both parties regarding the transfer of ownership and a delivery of the respective good (*Einigung und Übergabe*). Prof. Mayr, has neither explicitly nor implicitly agreed to transfer ownership, or any commercial rights, to Dr. Moss and/or NIH. Under the rules prevailing in the scientific research community the facts at hand exclude an assumption of an implicit (tacit – stillschweigend) transfer of ownership or license for commercial use of MVA-572 to Dr. Moss and/or NIH. Since also BN never agreed to transfer ownership or any commercial rights in MVA-572 to Dr. Moss and/or NIH, Dr. Moss and/or NIH were not free to use the MVA-572 strain and/or its progeny commercially.

37. Prof. Mayr or BN never provided the MVA-572 strain to Acambis, thus, Prof. Mayr or BN has not transferred ownership, or any commercial rights, to Acambis. Accordingly, Acambis was not free to use the MVA-572 strain and/or its progeny commercially.

VII. MY OPINION REGARDING GOOD FAITH DEFENCE

38. Dr. Moss or NIH could only become owner(s) on basis of Section 932 para.1 BGB if they were in good faith receiving the MVA-572 strain. However, according to Section 932 para.2 BGB the purchaser will not be in good faith "if he knew or due to gross negligence did not know that the MVA-572 strain did not belong to the seller." The letter, which Therion Biologics wrote to Prof. Mayr on February 26, 2002, where one can read: "Dr. Moss is willing to send us the virus but would like written permission from you before he sends us the virus", clearly reveals that Dr. Moss and NIH were fully aware of the legal status of MVA-572. CEF, i.e., that they had no title of ownership in it.

39. Good faith depends on the circumstances. For example, there was no money transaction in connection with the shipment of this strain. In any event, Dr. Moss and the NIH were put on notice by Prof. Mayr and BN prior to the provision of the MVA-572 strain and/or its progeny to Acambis and certainly before any commercial use has been made of it.

40. Acambis was not and cannot have been in good faith as required by German law. For example, the MVA dated 9 September 2002 explicitly provides no warrant regarding freedom to operate and includes an indemnification clause to the benefit of the NIH. Acambis was put on notice by BN prior to receiving the MVA-572 virus strain regarding Bavarian Nordic's rights of Prof. Mayr's MVA viruses, and thus also regarding Prof. Mayr's rights to his man made MVA viruses, and certainly before any commercial use has been made of it. Acambis was further put on notice by the NIH of claims made by Bavarian Nordic and Prof. Mayr regarding legal rights to the MVA-572 virus strain prior to receipt of this particular strain and certainly before any commercial use has been made of it. Ignorance of the law is no defense to liability under the law.

41. Accordingly, Dr. Moss and/or NIH or Acambis cannot be considered bona fide purchasers and were therefore not free to use the MVA-572 strain and/or its progeny commercially.

Respectfully submitted,

Prof. Dr. Dres. h.c. Joseph Straus

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S, Plaintiff, v. ACAMBIS INC. and ACAMBIS PLC, Defendants.	Civil Action No. 05-614 (SLR)

SUPPLEMENTAL EXPERT REPORT AND/OR LEGAL OPINION OF

PROF. DR. DRES. H.C. JOSEPH STRAUS

I. INTRODUCTION

1. My name is Joseph Straus and I have been retained as a legal expert on German Law by Bavarian Nordic A/S ("BN") in connection with the above-referenced case in the United States District Court for the District of Delaware to study and provide opinion on certain issues relating to ownership to and/or intellectual property rights in certain Modified Vaccinia Virus Ankara ("MVA") strains and vaccines. On October 2, 2006 I submitted my Expert Report and/or Legal Opinion.

2. After having read the Expert Report and/or Legal Opinion of Prof. Dr. Winfried Tilmann of November 10, 2006, I wish to submit the following supplementary statement.

II. EXPERT REPORT AND/OR LEGAL OPINION OF PROF. DR. WINFRIED TILMANN

3. Professor Tilmann correctly stated that for an ownership transfer, according to § 929 BGB (Bürgerliches Gesetzbuch – Civil Code), there need only be two elements: (1) change of possession and (2) agreement as to the transfer of ownership of the specific personal property transferred (No. 17).

4. Whereas no dispute exists as to the fact that in the specific samples of MVA-572 sent from Professor Mayr to Dr. Moss of the National Institutes of Health (NIH) a change in possession took place, Professor Tilmann advocates also the view that the facts of the case at issue speak for themselves that Prof. Mayr and Dr. Moss also agreed as to the transfer of ownership of the specific personal property in the respective samples. According to Professor Tilmann:

> "Prof. Mayr sent the MVA-strains to Dr. Moss/NIH at the end of August 2001 without any commentary, especially not suggesting that Dr. Moss should return them or otherwise refrain from exercising ownership over the strains. He clearly did not want these MVA-strains returned, because they were to be used by the recipient. Nor did Prof. Mayr in his letter of September 12, 2001 sent to Dr. Moss after having sent the material to him, request any return of the changed or unchanged material. He had sent these MVA-strains once and for all." (No.19).

Prof. Tilmann goes on by stating:

> "This and the acceptance of the material and the letter of September 12, 2001 by Prof. Mayr can only be understood and interpreted as establishing an agreement regarding transfer of ownership. It was neither a lease (where there is no change in ownership

because there is a duty to hand back the material), nor a service contract (no change in ownership, duty to hand back the material). Prof. Mayr gave the material and did not expect to see his "property" preserved, which would include a right on his side to call the material back. That Prof. Mayr gave up possession is given. Prof. Mayr also clearly wanted Dr. Moss/NIH to 'have and to use' the MVA-572-strains. This fulfills the necessary elements for transfer of ownership (the latter being defined in § 903 BGB as being able to do with the object what you want and to exclude others from any intrusion)." (No. 20)

5. Prof. Tilmann then interprets my Expert Report in a way as if my arguments against transfer of ownership would relate to what he calls "any underlying causal purpose-agreement." (No. 23)

6. In order to avoid any misunderstanding, I, as not disputed by Prof. Tilmann, stated that according to the so-called *Abstraktionsprinzip* both transactions (i.e. sales contract and transfer of ownership) are legally independent transactions. Moreover, I emphasized that "a provision of an MVA-572-strain for research purposes certainly does not automatically qualify as a transfer of rights for commercial purposes unless there is a specific agreement between the parties to that effect, either explicitly or based on research or industry practice." (No. 32)

7. Finally, I stated that Prof. Mayr has *neither explicitly nor implicitly agreed to transfer ownership or any commercial rights*, to Dr. Moss and/or NIH (No. 36). Thus, in my statement the transfer of ownership in MVA-572-strain has by no means been made dependent on an explicit agreement between Prof. Mayr on the one hand and Dr. Moss or NIH on the other, be it as regards the transfer of ownership, be it as regards any other "underlying agreement".

III. TRANSFER OF OWNERSHIP IN MOVABLES UNDER § 929 BGB

8. According to the case law of the German Federal Supreme Court (BGH) for the *transfer of ownership* in movables it is required that

> "the owner of the thing deliver it to the acquirer and that both agree that the ownership is transferred: It suffices, when the will for the transfer of ownership is revealed from the circumstances. Whether the will to agree exists, is to be judged according to the general principles applicable to the interpretation of legal transactions [references omitted]."[1]

9. In other words, the question, whether an agreement between the parties concerned as to the transfer of ownership is to be confirmed, depends on the circumstances of the case at issue. This, it has to be emphasized, does not relate to the underlying "causal purpose-agreement" or "any underlying obligatory purpose-agreement," in Prof. Tilmann's words, but exclusively to the *separately* and *independently* required agreement as to *the transfer of ownership*. It is also understood that the movable thing in which the ownership is to be transferred has to be specifically individualized since only in such objects a possession is possible. Therefore, ownership transfer in a quota of a larger quantity is not possible. § 929 BGB requires a separation of the specific objects.[2]

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[1] 1990 NJW 1913, left column. In the original German: "... Zur Übertragung des Eigentums an einer beweglichen Sache [ist] erforderlich, dass der Eigentümer die Sache dem Erwerber übergibt und beide darüber einig sind, dass das Eigentum übergehen soll. Es reicht aus, wenn der Wille zur Eigentumsübertragung sich aus den Umständen ergibt. Ob dieser Einigungswille vorhanden ist, beurteilt sich nach den allgemeinen Grundsätzen der Auslegung von Rechtsgeschäften" [references omitted]. Cf. also Staudinger/Wiegand, 2004, § 929 No. 9 a), with further references.

[2] Erman/Michalski, § 929 BGB No. 2, with further references to the case law of the former Reichsgericht and the BGH.

10. In the case at hand the circumstances decisive for whether an agreement *as to the transfer of ownership in MVA-572* existed in the sense of § 929 BGB cannot be reduced to the circumstances taken into account by Prof. Tilmann, i.e. to the letter of Prof. Mayr to Dr. Moss dated September 12, 2001. Rather the following circumstances count:

(i) Prof. Mayr deposited the MVA-572-strain with the European Collection of Cell Cultures (ECACC) on *January 27, 1994*, accession number 94012707. Under the rules of ECACC, the deposited strains can be accessed and released without the depositor's consent, but only for use for research purposes.

(ii) Prof. Mayr on *May 28, 1996* signed an Agreement with Bavarian Nordic, in which under No. 1.3 he offered Bavarian Nordic the *exclusive* and *sole access to MVA Vaccine Stock* and MVA Viral Stock in his possession. However, under the very same provision of that agreement it is stated:

> "Bavarian Nordic recognizes that, in the scientific community, there is a growing interest in performing basic non-commercial research including the MVA-vector. Bavarian Nordic agrees not to unreasonably use its exclusivity to the MVA-system to hinder basic research by third party non-commercial academia including the MVA-system by rejecting access to the MVA-system."

This provision is found literally in all agreements which Prof. Mayr subsequently concluded with Bavarian Nordic in June 1996, June 1999, June 2001 as well as June 2003.

(iii) With a letter dated *September 18, 1995*, Therion Biologics requested Prof. Mayr his MVA-strain of Vaccinia Virus. In the request they emphasized that "we will use this material 'for research purposes only.'" With the accompanying letter of September 26, 1995 Prof. Mayr sent to Mrs. Linda Gritz of Therion Biologics Corporation the requested material, without any further explanation.

(iv) With a letter dated *September 14, 1995*, i.e. after the MVA-572 had been deposited with ECACC, Dr. Moss, Chief of the Laboratory of Viral Diseases of NIH, wrote to Prof. Mayr:

> "As you know, my laboratory has been using the MVA-strain of Vaccinia Virus *to make recombinant expression vectors*. Until now, we have been using the virus that was brought here by Gerd Sutter. However, it would be useful to have either an official vial of seed virus used for human vaccine production or a vial of vaccine. If you could supply me with such virus including lot number and date of preparation, it would be greatly appreciated. For your convenience, you could use my Federal Express Numbers to send the material. …
>
> Thank you for considering this request."[3]

(v) With the accompanying letter of *September 19, 1995*, Prof. Mayr sent Dr. Moss the required material, without any comments.

(vi) With a letter dated *August 3, 2001* Dr. Moss again wrote to Prof. Mayr:

> "Gerd Sutter told me the good news that you have been able to locate an early sample of MVA in your freezer and have agreed to send it to me. I wish to thank you for your generosity in this regard. As you are aware, MVA has taken on a new life as the premier vaccinia virus vector. I have enclosed a reprint of a recent paper that clearly illustrates the great potential value of MVA. …
>
> Again, I thank you for your kindness in this matter."

(vii) Prof. Mayr with accompanying letter of *September 12, 2001*, without specific comments sent the requested material to Dr. Moss.

(viii) National Institutes of Health (NIH) is the largest research institution in life sciences not only in the US, but worldwide. It is a non-for profit institution.

Because of its first-class cutting edge research, Prof. Mayr sent, supported by a grant which he received from the German Public Funding Authorities, his collaborator Gerd Sutter, to NIH, primarily with the task to sequence their MVA-strain of Vaccinia Virus.

(ix) NIH has an Office of Technology Development at the National Institute of Allergy and Infectious Diseases (NIAID). According to its homepage[4]

> "The NIAID Office of Technology Development (OTD) accomplishes technology transfer by facilitating the transfer of significant research advances and resources to the broader scientific community and the development of collaborative relationships between NIAID scientists, industry, and academia. NIAID uses various mechanisms to accomplish these ends, including Material Transfer Agreements (MTAs), Co-Operative Research and Development Agreements (CRADAs), Materials-CRADAs (M-CRADas), Confidential Disclosure Agreements (CDAs), Clinical Trial Agreements (CTAs), Drug Screening Agreements (DSAs), Research Collaboration Agreements (RCAs), and, through the NIH Office of Technology Transfer (OTT), the patenting of inventions and the negotiation of various license agreements."

(x) NIAID's OTD, as the commercial exploitation arm of NIH's NIAID never on its own initiative approached Prof. Mayr, nor was it, at least not visibly, involved in any communication between Dr. Moss and Prof. Mayr.

(xi) On *January 10, 2002* Dr. Linda Gritz, Principle Scientist of Therion Biologics wrote to Prof. Mayr, *inter alia*:

> "As per our telephone conversation, I am writing to request several vials of your MVA-strain of Vaccinia Virus that were made before 1980. We

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[3] Emphasis added.

[4] http://www.3.niaid.nih.gov/about/organization/odoffices/omo/otd/about/detel/default... (last visited November 28, 2006).

are interested in testing recombinant MVA for research in human clinical trials and I am very grateful for the 1983 stocks of MVA that you sent us several years ago. However, the United States Food and Drug Administration is concerned about the possible presence of prions in cell culture material derived in Europe after 1980. Therefore we are requesting earlier (1973 or 1974 or earlier?) stocks of your MVA. We will use this material for research purposes only."

(xii) In a letter dated February 26, 2002, the same Dr. Gritz of Therion wrote to Prof. Mayr:

"As per our telephone conversation, I am writing about the MVA virus, MVA-572. CEF v. 22.2.74, that you sent to Dr. Bernard Moss. Dr. Moss is willing to send us the virus but would like *written permission from you before he sends us the virus*.

Therefore I would greatly appreciate it if you would send such a letter, giving Dr. Moss permission to provide MVA-572.CEF v. 22.2.74 (and derivatives) to Therion, at your earliest convenience: [here follow the mailing address of Dr. Moss and Dr. Gritz]."[5]

(xiii) Professor Mayr neither required nor received any compensation for the transfer of possession in MVA-572 to Dr. Moss/NIH.

11. The circumstances of the case at hand, to my understanding, do not allow any other conclusion as that there *was neither an explicit nor an implicit agreement between Prof. Mayr and Dr. Moss/NIH that the ownership in the sample of MVA-572*, i.e. the complete control to dispose of it at will, *in particular to commercially exploit*, e.g. *license or sell the progeny* of the MVA-572 strain, the *possession* of which Dr. Moss has acquired in 2001, were to

[5] Emphasis added.

be transferred to Dr. Moss and/or NIH.

12. Not only had Prof. Mayr already in 1994, i.e. before sending any MVA strains to NIH's Dr. Moss, deposited the MVA-572 virus strain with the ECACC, thus made it available for research purposes to the academic community, he also entered the contractual obligation to allow access for commercial purposes to that material to Bavarian Nordic on *an exclusive basis* in the above mentioned agreement of June 1996. Thus, assuming that Prof. Mayr agreed upon transfer of ownership in the sample sent to NIH in 2001 is clearly in contradiction with all the circumstances of the case at hand. It implies the assumption that Prof. Mayr would have on purpose treated Dr. Moss and/or NIH in a privileged way as compared to other academic researchers seeking access to MVA-572, and also that Prof. Mayr *knowingly* violated his contractual obligations with Bavarian Nordic. Moreover, such an assumption is also *clearly inconsistent with the denial of Dr. Moss* to send samples of MVA-572 virus to Therion Biologics without *written permission* of Prof. Mayr.

13. The *ex post* attempts of NIAID and its OTD, which first requested Dr. Moss not to reply to complaints raised by Prof. Mayr (see letter of Dr. Moss of April 23, 2003), to claim that NIH acquired, *free of any charge and any payment of any consideration and without any MTA* all rights with respect to the material, progeny and derivatives of the MVA-572.FHE-22.02.1974 that Prof. Mayr supplied to Dr. Bernard Moss in late summer 2001 (letter of Dr. John R. La Montagne of December 10, 2002), *find no support in the circumstances of the case*. Prof. Mayr had no reason to treat Dr. Moss and/or NIH as a non-for profit research institution any differently than any other colleague, who approached him with a request to access his MVA viral strains. There should be no doubt, especially in view of the circumstances described, that Prof. Mayr for sure would have acted differently if NIAID's OTD would have been involved in

the transfer of the respective strains on the side of Dr. Moss and NIH.

14. Without going into details, it should be added that the assessment of the alleged ownership in MVA-572.FHE-22.02.1974, by NIH's NIAID itself seems to be reflected in the MTA signed between NIAID and Acambis, Inc., in 2002, where as regards that material, No. 10 reads as follows:

> "NO WARRANTIES, EXPRESSED OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS PROVIDED TO RECIPIENT UNDER THIS AGREEMENT, OR THAT THE MATERIALS OR COMMERCIAL PRODUCTS MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY PARTIES. Recipient accepts transfer of the material "as is", and NIAID does not offer any guarantee of any kind."[6]

15. For the sake of completeness only, it should finally be observed that in view of the specific properties of the material at hand, namely *its ability to be reproduced in a biological system*, thus, its use, even for research purposes only, being dependent on continuous reproduction of the strain, all comparisons of any acts typical of ownership in movables, *which are not biological material*, are vastly misplaced and, as a rule, not suitable to contribute to an adequate understanding of the issues at hand. This relates in particular to acts such as destruction, return of the material, etc. Not surprisingly, many distributors of biological materials, who for instance use the so-called lease-license model, do not even require or expect the return of the physical materials. The recipient may destroy the materials or retain them

[6] Emphasis in the original.

indefinitely. But restrictions apply to further transfers by the recipient.[7] Thus, the fact alone that a recipient of biological material may destroy it or retain it indefinitely, does not bear any significance as to the ownership in such material.

IV. CONCLUSION

16. Under the case law of the German Federal Supreme Court (BGH) in the case at hand, as a consequence of the *clear lack of a respective agreement*, no transfer of ownership from Prof. Mayr to NIH/Dr. Moss in MVA-572 has taken place under § 929 BGB. This lack of agreement as to the transfer of ownership ("Einigungswille") relates exclusively and specifically to the so-called "Verfügungsgeschäft", i.e. the transfer of ownership *in abstracto*.

Munich, November 29, 2006

Prof. Dr. Dres. h.c. Joseph Straus

[7] O'Connor, The Use of MTAs to Control Commercialization of Stem Cell Diagnostics and Therapeutics, Berkeley Technology Law Journal Vol. 21:3, 1017 ss., at 1019, 1020 [2006].

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 29th day of November 2006, copies of BAVARIAN NORDIC'S SUPPLEMENTAL EXPERT REPORT AND/OR LEGAL OPINION OF PROF. DR. DRES. H.C. STRAUS were served as follows:

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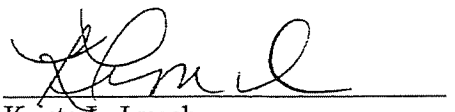

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